IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

- - -

UNITED STATES OF AMERICA ex rel. TOASH GOHIL,	:	CIVIL ACTION NO. 02-2964
Plaintiff	:	
v	:	
AVENTIS PHARMACEUTICALS, INC.,	:	Philadelphia, Pennsylvania
	:	February 19, 2014
Defendant	:	9:14 a.m.

- - -

TRANSCRIPT OF HEARING
BEFORE THE HONORABLE LAWRENCE F. STENGEL
UNITED STATES DISTRICT JUDGE

- - -

APPEARANCES:

For the Plaintiff:

CARL D. POPLAR, ESQUIRE
1010 Kings Highway South
Building Two
Cherry Hill, NJ 08034

DAVID C. KISTLER, ESQUIRE
NICHOLAS CARL HARBIST, ESQUIRE
Blank Rome LLP
301 Carnegie Center
Princeton, NJ 08540

STEPHEN M. ORLOFSKY, ESQUIRE
Blank Rome LLP
One Logan Square
130 North 18th Street
Philadelphia, PA 19103

Transcribers Limited
17 Rickland Drive
Sewell, NJ 08080
856-589-6100 • 856-589-9005

APPEARANCES: (Continued)

For the Defendant: RICHARD L. SCHEFF, ESQUIRE
MICHAEL B. HAYES, ESQUIRE
Montgomery McCracken
Walker & Rhoads LLP
123 South Broad Street
Philadelphia, PA 19109

ROBERT J. McCULLY, ESQUIRE
Shook Hardy & Bacon LLP
2555 Grand Boulevard
Kansas City, MO 64108

- - -

Audio Operator: Laura Buenzle

Transcribed By: Michael Keating

- - -

Proceedings recorded by electronic sound recording; transcript produced by computer-aided transcription service.

- - -

(The following was heard in open court at 9:14 a.m)

THE COURT: Good morning.

ALL: Good morning, Your Honor.

THE COURT: Please be seated. We are here this morning for argument on a motion to dismiss in this matter that was recently reassigned to my docket and which was the subject of a telephone conference recently, and counsel indicated they would like an opportunity to present argument, and I'm very grateful for that to get a chance to review these issues with you.

Let me just make sure I know who's here. Steve Orlofsky, good morning.

MR. ORLOFSKY: Good morning, Your Honor.

THE COURT: Carl Poplar.

MR. POPLAR: Good morning, Judge.

THE COURT: Good morning. Nick Harbist.

MR. HARBIST: Good morning, Your Honor.

THE COURT: Good morning. And David Kistler.

MR. KISTLER: Good morning, Your Honor.

THE COURT: Good morning. And Richard Scheff.

MR. SCHEFF: Good morning, Your Honor.

THE COURT: Good morning. And Rob McCully.

MR. McCULLY: Yes, Your Honor.

THE COURT: Good morning.

MR. McCULLY: Good morning.

THE COURT: Daniel Donvidani (ph).

MR. DONVIDANI: Good morning, Your Honor.

THE COURT: Good morning. And Michael Hayes.

MR. HAYES: Good morning, Your Honor.

THE COURT: Good morning. Well, this is the defendant's motion to dismiss, so will you be beginning, Mr. Scheff?

MR. SCHEFF: I will be --

THE COURT: Okay.

MR. SCHEFF: -- but I won't be ending.

THE COURT: Okay.

MR. SCHEFF: If I could, may it please the Court, my name is Richard Scheff. I'm from Montgomery McCracken, along with my co-counsel, Rob McCully, who is seated at counsel table, from Shook Hardy. We represent the defendants and movants, Sanofi-Aventis Aventis, Inc. and Aventis Pharmaceuticals.

With the Court's permission, Mr. McCully and I will divide the argument. I'm going to talk about the case and factual chronology. I'll be addressing our motion to dismiss based on Mr. Gohil's release --

THE COURT: Right.

MR. SCHIFF: -- which we believe bars him from being a relator in this case. I will mention very briefly another release argument that we made in our brief relating to the drug Anzemet, which really was the subject of the original qui tam complaint and the first amended complaint.

I will argue our subject matter jurisdiction arguments on original source, saying that the cause of certain public disclosures that were made, Mr. Gohil is not the original source of the information upon which the second amended complaint is based.

Mr. McCully is going to address the argument under Federal Rule of Civil Procedure 9(B), that is pleading with particularity, as well as Mr. Gohil's inability to state a claim under 12(b)(6) and address the conspiracy argument or conspiracy claim.

So, let me start with just some factual background, if I could, please. As the Court is aware, the second amended complaint purports to allege a nationwide fraudulent scheme whereby Aventis sales representatives marketed Taxotere, which is a cancer drug, off-label and encouraged doctors to prescribe the drugs off-label by offering them grants and other forms of money which the relator says are kickbacks.

The second amended complaint alleges that

scheme from the period 1996 to 2004. Mr. Gohil, however, admits that he only began promoting Taxotere in late 1999, I think November or December of 1999, and this occurred after the merger of two other companies, Hoechst, Marion and Roussel, the company that Mr. Gohil worked for as a sales rep, and Rhone-Poulenc Rorer merged to form Aventis.

Now, the rights to Taxotere, which is the drug really prominently featured in the second amended complaint was brought to Aventis by Rhone-Poulenc Rorer, which was not the company that Mr. Gohil worked for. And the company that Mr. Gohil worked for marketed the drug Aventis -- I'm sorry -- marketed the drug Anzemet --

THE COURT: Right.

MR. SCHIFF: -- and that's what he brought to the table. Mr. Gohil resigned from Aventis on June 10th, 2002.

So the second amended complaint addresses a fraudulent scheme that supposedly starts approximately four years before Mr. Gohil became responsible to promote Taxotere and extended for two years after he left the employ of Aventis. So the first four years of the so-called scheme, 1996 through 1999, as I said, Mr. Gohil was not even employed by the company that sold

Taxotere.

The original qui tam complaint filed by Mr. Gohil was filed on May 17th, 2002, and that was before he left the employ of Aventis because he resigned on June 10th. On July 23rd, he filed his first amended complaint. In looking at those complaints --

THE COURT: July 23rd of what --

MR. SCHIFF: -- and focusing --

THE COURT: -- year again?

MR. SCHIFF: 2002.

THE COURT: Right.

MR. SCHIFF: In looking at those complaints and focusing on the first amended complaint, virtually every factual allegation is limited to the two-year time period of his employment at Aventis, and the only allegation which supposedly pre-dates his employment at Aventis is paragraph 125 of the first amended complaint where there is a general allegation regarding a multi-year grant to a breast oncology division of a local hospital here. Those payments supposedly were made prior to the merger of Hoechst, Marion and Rhone-Poulenc.

If you also look at the first two complaints that were filed, the original qui tam complaint as well as the first amended complaint, the emphasis was on the

drug Anzemet, not Taxotere, and that makes sense because that was the drug that Mr. Gohil brought to the table and had promoted for years before Aventis even came into existence.

The allegations regarding Taxotere in the first amended complaint were limited to isolated instances of grants being given to one doctors group and to a hospital supposedly in return for prescriptions for Taxotere.

Now, around this same time in August of 2002, so this is after Mr. Gohil resigns, after Mr. Gohil files he qui tam complaint, and after he files the first amended complaint, he files an action under New Jersey law for retaliation, a CEPA action, claiming that Aventis had retaliated against him for raising certain objections to sales promotional activities, and that complaint in the CEPA case is Exhibit 2 to our motion to dismiss.

Now, the CEPA case was very actively litigated, and Mr. Gohil was represented by one of the counsel in this case, Mr. Poplar. And following extensive discovery, that is document production, multiple depositions, and a full briefing on a motion for summary judgment that had been filed by Aventis, the CEPA case eventually settled. The date of that

settlement and the date of the broad release that Mr. Gohil signed was October 19th, 2005.

Now, of course, all along while the CEPA case was pending and after it concluded, Mr. Poplar was in regular contact with the government in an attempt to convince the government to intervene in Mr. Gohil's still sealed qui tam complaint, but notwithstanding those efforts, the government formally declined to intervene in that case on August 15th, 2006, almost a year after the CEPA case resolved.

A month later in September of 2006, the seal was lifted on the first amended complaint and Mr. Gohil was ordered to serve that complaint. But rather than do that, he filed a motion for leave to file his second amended complaint based on "new evidence." Those are Mr. Gohil's words, not our words, and at the same time, he asked the government for the same reason to reconsider its decision not to intervene.

Now, I want to give the Court some dates, and I know I've been doing that, but this is sort of a date-intensive case, if you will.

THE COURT: Well, when was --

MR. SCHIFF: So --

THE COURT: When was the complaint unsealed?

MR. SCHIFF: Complaint --

THE COURT: This is the first --

MR. SCHIFF: The --

THE COURT: -- amended complaint, right.

MR. SCHIFF: The first amended complaint was ordered to be unsealed in August of 2006.

THE COURT: Right, okay.

MR. SCHIFF: The seal was lifted in September -- I'm sorry, September of 2006.

THE COURT: This is about a month after the government --

MR. SCHIFF: Declined.

THE COURT: -- declines to intervene?

MR. SCHIFF: That is correct.

THE COURT: Okay.

MR. SCHIFF: Now, what is apparent -- and the motion seeking to leave to file the second amended complaint based on new evidence was filed November 7th, 2006, so approximately two months later. If the Court looks at Exhibit 7 to our motion to dismiss, and I know this is a very voluminous record, Your Honor.

THE COURT: Go ahead.

MR. SCHIFF: That letter is dated November 9th, 2006, so it's two days after the motion for leave to file the second amended complaint. It's from a lawyer at the Justice Department named Jamie Yavelberg,

and what she is doing is she is informing Mr. Poplar that Mr. Gohil is not going to be "first to file" with respect to Anzemet, which really was the subject, the primary subject, of the original qui tam in the first amended complaint. And she's saying to him you're not going to be first to file.

And what that means is -- and there was a settlement that Aventis was closing with the government relating to promotional activities of Anzemet at that very same time, and we've included a copy of the anzemet release as Exhibit 6 of the -- to the motion to dismiss.

The importance of this letter because it ties into why the second amended complaint is filed and why it is based on so-called new evidence is that Ms. Yavelberg is telling Mr. Poplar your client is not first to file on Anzemet. And what that means is he's not going to get any money from the settlement. He's not going to be a relator who qualifies for money in that settlement.

And so what has to happen in order for Mr. Gohil to go forward, the government's now declined to intervene, is he's got to find a new theory because he's got to be the first to file.

And so he files the motion with the Court for

leave to file the second amended complaint, which we contend is a new theory at that same time, contending that it's based on new evidence. So that's the factual backdrop to why the second amended complaint is filed.

The government has declined to intervene. The government has told Mr. Poplar that his client is not first to file so he's out of the money and they've got to come up with a new theory, and this is based on, in their words, new evidence.

So in early 2007, the second amended complaint was filed under seal. The government, after a request by Mr. Gohil to review that, again, declined to intervene.

Now, the new evidence that was referred to by Mr. Gohil to this Court and to the government was evidence that Mr. Gohil and his counsel obtained during the discovery of the CEPA case, the New Jersey case that had settled in 2005.

Specifically, what was provided to the government was a lengthy statement of facts in opposition to the motion for summary judgment, as well as five accompanying volumes of documents from the CEPA case and deposition testimony from Mr. Gohil.

If you look at the statement of facts that was submitted in opposition to the motion for summary

judgment and compare that to the second amended complaint, they are strikingly similar, and it is from that statement of facts filed in the CEPA case that the scope of the complaint in this case, as alleged in the second amended complaint, expands dramatically in time early to 1996 and then ending in 2004, and the substance of that second amended complaint as well shifts entirely to Taxotere from Anzemet because he's not first to file on Anzemet so he's not in the money, and now alleges a new scheme of off-label promotion, all coming from the discovery in the CEPA case.

So the documents, that is the release from the CEPA case, the statement of facts files in the CEPA case in opposition of the motion for summary judgment, and the letters to the Justice Department from Mr. Poplar, are very important in this case, both with respect to the release argument that I'm about to make and the original source argument that I will make in a moment.

So, let me turn to the release argument. November 19th, 2005, Mr. Gohil files or signs a broad release in order to settle the CEPA case. It is on the basis of that document, Your Honor, that this case must be dismissed as to him and he cannot be a relator.

He signed that release, it is Exhibit 3 to

our motion. It contains broad language releasing any claims that Mr. Gohil has against Aventis based on any and all claims, charges, causes of actions, or liabilities of any nature whatsoever. The release by its terms are controlled by New Jersey law.

The case of Isetts versus Roseland, which is cited in our brief, interprets virtually identical language and says that the any and all broad language of the release allows for no exception and it includes everything.

Now, notably, in response to our release argument in our motion to dismiss, Mr. Gohil does not challenge at all the broad scope of that document, and so I would say, Your Honor, that he has conceded that that document is broad in scope and that New Jersey law says that it releases any and all claims.

So the enforceability of that document as to Mr. Gohil is government by the Supreme Court case of Rumery. In Rumery, the Supreme Court says a case by case analysis has to be conducted, but the release should be enforceable unless outweighed by public policy considerations. In this case, there are no public policy considerations that weigh in favor of not enforcing that release against Mr. Gohil.

Now, there is no Third Circuit case directly

on point concerning the application of the Rumery standard to releases in qui tam claims. But other circuits have addressed our facts and, essentially, what it comes down to is whether the government had a full and fair opportunity to investigate the claims at issue in the qui tam case.

Here, Mr. Gohil brought his contentions to the government first in the spring of 2002, actually on May 29th, 2002, and, in fact, at that time and in the months that succeeded the spring of 2002, Mr. Gohil provided more than 12,000 pages of documents to the government, 11 CDs containing information, and five videotapes that he had collected during his two-year tenure with Aventis. He gave that all to the government in connection with his original filing and with the first amended complaint in 2002.

Now, we only learned that that occurred in 2010 when we finally got some discovery that we were entitled to, but that was the volume of information presented to the government in 2002.

In addition, in March of 2005, the Department of Health and Human Services Office of Inspector General subpoenaed from Mr. Gohil any additional evidence or information that he obtained during the discovery in the CEPA case, and that subpoena is

attached to our motion as Exhibit 5.

So as of mid-2005, the government had all of Mr. Gohil's documents that he had obtained during his employment, the 12,000 pages, 11 CDs, and five videotapes, and they had all of the evidence from the CEPA case.

So, the government had this information for three and a half to four years while they considered whether or not to intervene in this case, and they decided first in 2006 not to intervene, and then decided again in 2007 after a request was made again, again, not to intervene.

So it cannot be disputed that the government had more than sufficient time to investigate Mr. Gohil's allegations of fraud and they chose not to proceed.

So, under the cases, and, again, not Third Circuit cases, but under the cases, and they're all cited in our brief, about the enforceability of releases in qui tam cases, the government had a full and fair opportunity to review the claims. They elected not to and, therefore, there is no public policy that should bar the enforcement of the release.

Now, Mr. Gohil, in response, argues that the Longhi case from the Fifth Circuit controls because he

filed his qui tam case before he executed the release and under the False Claims Act, the statute, therefore, precludes him from dismissing the qui tam action without the government and the Court's approval, and, therefore, he says the release -- the release cannot effectively dismiss the qui tam.

As we explained in our reply, and I'll say it to the Court again, we're not trying to bar the government from proceeding in this qui tam case. All we are trying to do is bar Mr. Gohil from proceeding in the qui tam case.

So the government's statement of interest, the only position that it takes with respect to the release issue is that if the claims are dismissed, that they be dismissed without prejudice. We have no argument with that. All we are seeking to do is enforce the release against Mr. Gohil and bar him as the qui tam relator.

So that's our release argument, broad release, government had adequate opportunity, sufficient opportunity to review the allegations, they twice chose not to intervene, no public policy reason not enforce it, and the claim should be dismissed without prejudice. If the government wants to proceed, the government can elect to proceed.

Now, we also argued -- and this will take about ten seconds hopefully. We argued in our brief that to the extent that the second amended complaint raised claims with respect to the drug Anzemet that those claims also were released because the government and Aventis had settled a case as to Anzemet, thereby releasing the government's claims.

Mr. Gohil's reply to that was that they weren't seeking any damages based on the promotion of Anzemet in the second amended complaint. With that representation, Your Honor, we don't believe that issue is any longer on the table. If they're not seeking damages based on Anzemet, there's nothing for them to proceed on. So that's the anzemet argument.

So let me get to the last argument that I'm going to make, which is a jurisdictional argument, subject matter jurisdiction. There are really two components to this.

One is raised in our brief, and one we recognized actually the other day as we were preparing for this oral argument. And because it's a subject matter jurisdiction argument it's not waived and can be raised at this time and certainly raised sua sponte by the Court.

With respect to original source, Your Honor,

the Court does not have subject matter jurisdiction over Mr. Gohil's claims because his second amended complaint is based on public disclosures and he is not the original source of the information.

31, U.S.C., Section 3730(e)(4)(A) says that a qui tam action cannot be based on publicly disclosed information unless the relator is also an original source of the information.

An original source must have direct and personal knowledge of the information upon which the allegations are based and he must or she must voluntarily provide that information to the government before the filing of the qui tam action.

Now, I want to just repeat that last phrase because that is the new basis for no subject matter jurisdiction in this court. The relator has to be the original source and they have to voluntarily provide that information to the government before filing the qui tam action. That didn't happen here.

The qui tam action was filed first and the information submitted later, and I'll provide the dates to the Court and the references in the record where that is the case and so there is no subject matter jurisdiction in this case because Mr. Gohil did not comply with the statute.

So let me turn to original source subject matter jurisdiction. There's a twofold analysis with original source. Number one, are the claims based on publicly disclosed information and, if so, is Mr. Gohil an original source?

So, let me again just sort of refresh the Court on the chronology. Original qui tam complaint filed May 17th, 2002. First amended complaint filed July 23rd, 2002. The first amended complaint does not allege a nationwide off-label promotion scheme for Taxotere. The focus is on Anzemet promotion and there are isolated grants mentioned with respect to Taxotere.

It does not allege any claims before Mr. Gohil's employment or after his employment. He litigates the CEPA case from 2002 to 2005. He obtains extensive discovery. He gives all that evidence to the government. And if I can refer the Court to Exhibits 9 and 10 attached to our motion to dismiss, they are letters from Mr. Poplar to the Assistant US Attorney, Paul Shapiro, in I believe May of 2005 and July of 2005, providing all of the evidence from the CEPA case.

The CEPA case then settles. The government does not intervene. I'll reference the Court again to that Exhibit 7, the letter from Ms. Yavelberg of the Department of Justice telling Mr. Poplar your client is

not first to file with Anzemet so you're out of the money, and that's why they have to come up with a new theory on the second amended complaint. So the new evidence, which is used as the basis for the second amended complaint, is the evidence for the CEPA case.

Now, how do we know that beyond comparing all the documents, and you can compare the statement of facts for the summary judgment motion. You can compare the second amended complaint to see how they track each other. You can see the differences from the first amended complaint. You obviously can see the difference in scope of time, the shift of focus of the scheme from Anzemet to Taxotere.

But Exhibit 10, it's a July 20th, 2005, letter from Mr. Poplar to Mr. Shapiro, and it's apparent that they're in contact. And Mr. Poplar refers to the employment lawsuit, that is the CEPA lawsuit, and he says we have discovered information responsive to your subpoena that refers to Aventis' use of grants to influence medical professionals to purchase Aventis products. That's arguably in the first amended complaint.

This letter will briefly discuss some of the discovery that documents this action. He then goes on to say "We should point out that this information was

learned through the discovery we obtained in the context of the employment lawsuit." So it's through the lawsuit, not for Mr. Gohil, because, and this is important language, Your Honor, the second sentence of the second paragraph, "Because that lawsuit primarily involves the separate issue of off-label marketing, our ability to inquire about Aventis' use of grants was limited."

The theory in the second amended complaint is that off-label marketing scheme, coming directly from the CEPA case, and Mr. Poplar is acknowledging that it is a separate issue of off-label marketing, which is the subject of the CEPA case, and it is that information which forms the basis for the second amended complaint. So that information goes to the government. Of course, the government declines the case again, as we know.

So under the Zizic case, Z-I-Z-I-C, from our circuit, the standard by which the Court must evaluate this jurisdictional issue is are there public disclosures? Do the facts come from public disclosures, and in doing so the Court can examine evidence outside the pleadings. And once those public disclosures are established, then it is Mr. Gohil's burden of persuasion to establish jurisdiction.

Under the Ducksberry case, again, cited in our brief, this is a District of Massachusetts case, district court, the False Claims Act is supposed to be strictly construed with doubts resolved against jurisdiction.

Again, back to our circuit, the Atkinson case and the Feldstein case, the Court must follow the following procedure. First, determine that a previous public disclosure exists, then determine whether the latest qui tam complaint is "based upon" the public disclosures. And the case law is clear that "based upon" means even based on -- based upon or substantially similar.

If that is the case, then the action can proceed only if Mr. Gohil has direct and personal knowledge and has voluntarily provided the information to the government before the qui tam action is filed.

So the public disclosures in this case, I'm going to break this up, for the pre-employment time period you've got two public disclosures. You've got all the discovery from the CEPA case, from the New Jersey employment case. Information obtained in litigation is a public disclosure. It's not direct and personal knowledge.

And there was a 1997 Wall Street Journal

article, and that is also attached as an exhibit to our motion where it discloses another lawsuit that was filed regarding a scheme of off-label promotion and the giving of grants connected to Lovenox and Taxotere. So that's the pre-employment time frame. Both qualify as public disclosures, a media report, litigation, or discovery in litigation.

For the post-employment time period, that is after June of 2002, again, we have the discovery from the employment case, the CEPA case, we have letters from the FDA, from what's called DDMAC, and DDMAC -- and it's now called something else. But DDMAC was a division within the FDA that monitored the promotional activities of pharmaceutical companies.

And when DDMAC had information that a pharmaceutical company was not complying with the rules relating to promotion they had two types of letters they could issue, one was called an untitled letter and the other was called a warning letter. And we've got DDMAC letters in this case as well. They're detailed in the second amended complaint.

Those DDMAC letters are available publicly on the FDA website. So they are public disclosures as well. We also have an admission with respect to the DDMAC letters that they were obtained by counsel during

counsel's investigation, certainly not direct and personal knowledge for Mr. Gohil.

Lastly, again, post-employment, we have a brochure, an Aventis brochure that allegedly Mr. Gohil saw in a doctor's office somewhere in South Jersey. That brochure was sitting on a table in a reception area, certainly a public disclosure.

All of these materials, the media reports, the brochure, the DDMAC letters, the discoveries from the CEPA case, all under the statute qualify as public disclosures.

Again, if you track or if you look at the second amended complaint and look at the statement of facts from the CEPA case, they are remarkably similar. The second amended complaint alleges a completely new scheme that is not detailed in the original complaint or the first amended complaint. It expands the time period dramatically.

Completely different emphasis, not on Anzemet, now on Taxotere, and that scheme actually that you see alleged in the original qui tam complaint and the first amended complaint I would also argue is disclosed in that Wall Street Journal article as well. And so that would be a public disclosure as to the original and the first amended complaint if they were

active in this case, which they are not.

The icing on the cake for all of this is, of course, that Exhibit 10, the July 20th letter from Mr. Poplar to Mr. Shapiro where he says the employment case is a separate off-label marketing issue. That's certainly a concession by Mr. Poplar that even he viewed it as a separate issue than what had been alleged in the first qui tam complaint and the first amended complaint.

Now, what Mr. Gohil does in response is he does what he calls a claim by claim analysis, which is referred to in the cases, and he says I raised the same claims in the first amended complaint as I did in the second amended complaint.

The problem is is if you look at the facts, they are significantly different from one complaint to the other. And what the case law says, and I think it's the Rockwell case, is that you can't allege a scheme in a conclusory manner sort of as a place holder to preserve a claim and then find out facts later from a public disclosure and then file an amended complaint and then all of a sudden allege a new scheme. That's not what the False -- that's not what the False Claims Act is all about.

And that's exactly what Mr. Gohil tried to do

in this case. He tried to assert a trivial claim of fraud with respect to Taxotere in an attempt to preserve that claim, but in examination of the first amended complaint, the second amended complaint, the statement of facts, and Mr. Poplar's admission demonstrate it's a separate scheme, and it's a scheme that Mr. Gohil does not have direct and personal knowledge of.

So, he doesn't have direct and personal knowledge of the information and the discovery from the CEPA case. He doesn't have direct and personal knowledge from the information that comes out of the Wall Street Journal article. The DDMAC records are on the public record. And the brochure is sitting in a doctor's office, again not direct and personal knowledge.

Mr. Gohil says with respect to the time period before he was employed that he learned that the conduct was the same from speaking with other employees. Again, that doesn't qualify as direct and personal knowledge.

Remember, at that point in time, he did not even work for the company that promoted Taxotere. So for those reasons, the Court must dismiss this case because Mr. Gohil is not an original course.

So let me circle back to the argument that we did not raise in our brief, and, again, we recognized it as we were preparing for this oral argument. Part of that original source, statute, the False Claims Act, requires that the relator disclose his information forming the basis of his allegations to the government before he files his qui tam complaint. His qui tam complaint was filed or his original qui tam complaint was filed May 17th, 2002.

The disclosures were made on May 29th, 2002, 12 days later. We know that because we have a letter to Mr. Sheenan, who then I believe was the chief of the Civil Division at the US attorney's office. From someone in Mr. Poplar's office, Mr. Paron (ph), we obtained that through discovery and we also know that because in supplemental answers to interrogatories provided by Mr. Harbist in October of 2010, he says in response to interrogatory number two and then thereafter provides dates that the first disclosure was May 29th, 2002, which is consistent with the letter from Mr. Poplar's office that we got through discovery. So, again, on that basis alone there is no subject matter jurisdiction in this case and the case must be dismissed.

Now, obviously, counsel has all lived with

this case for a long time and this case is just coming to the Court. But, there is one other sort of chronology I want to share with the Court because it explains, in addition, why this all happened the way it happened.

We know that Mr. Gohil is told he's out of the money on Anzemet so there has to be a shift of theory. We fought hard to get that information and it took us years to get that information from Mr. Gohil in this case. We did not come on that evidence easily.

We are asked for original source discovery through written discovery originally in 2008. We got no meaningful responses. We got broad objections and privilege assertions. We filed a motion to compel with Judge Tucker. She denied it. She said you can file this motion again, but I want you to take Mr. Gohil's deposition first. She ordered that on July 2nd, 2008.

We took Mr. Gohil's deposition on July 30th, 2008, and we were met with the same assertions of privilege and vague and contradictory responses. We renewed our motion to dis -- our motion to compel.

Judge Tucker reviewed Mr. Gohil's disclosure statements, all the letters, all the information that was provided to the government in camera, the ones that he claimed were privileged, and found no privilege, and

also said that Mr. Gohil had stonewalled us. That was her language, not ours.

Mr. Gohil then appealed that to the Third Circuit. That appeal was dismissed as non-appealable. And, finally, in 2010, we completed the original source discovery and got the documents which demonstrate that Mr. Gohil is not an original source.

We got the key letters, we got the key communications with the government, we got the description from Mr. Poplar showing that it was a different issue that he was presenting when he was presenting evidence from the second amended complaint, and we finally got the timing of when the information was provided to the government, May 29th, 2002, 12 days after the qui tam complaint was filed.

So it was hard fought, but we found the evidence. Mr. Gohil is not an original source. This Court has no subject matter jurisdiction and the case has to be dismissed.

So unless the Court has questions of me, I will then turn this over to Mr. McCully to address the 9(B) issues, the 12(b)(6) issue, and the conspiracy claim.

THE COURT: Thank you, Mr. Scheff.

MR. SCHEFF: Thank you, Your Honor.

MR. ORLOFSKY: Your Honor, if I may?

THE COURT: Yes.

MR. ORLOFSKY: It might be a good idea for me, before Mr. McCully goes forward for me to address this portion of the argument so that Your Honor hears our response --

THE COURT: I'd be happy to do that.

MR. ORLOFSKY: -- rather than wait.

THE COURT: Yes. Let's hear from the plaintiff on the original source and the release.

MR. ORLOFSKY: I think it might be helpful for Your Honor to hear my response sooner rather than later to Mr. Scheff's arguments?

THE COURT: Yes, I think that's fine. Thank you, Mr. Orlofsky.

MR. ORLOFSKY: Thank you.

(Pause in proceedings.)

THE COURT: Will you be addressing the release and the --

MR. ORLOFSKY: Yes.

THE COURT: -- original source issues?

MR. ORLOFSKY: I'll be --

THE COURT: Okay.

MR. ORLOFSKY: -- addressing the arguments which --

THE COURT: Very good.

MR. ORLOFSKY: -- which Mr. Scheff made.

THE COURT: Okay.

(Pause in proceedings.)

MR. ORLOFSKY: Good morning, Your Honor.

THE COURT: Good morning.

(Pause in proceedings.)

MR. ORLOFSKY: Your Honor, you won't be surprised this morning to learn that I disagree with Mr. Scheff on just about every point that he made this morning, and let me -- let me first start with the -- with the release.

I think that as with any analysis, we first return to the statutory language. And the statutory language of the False Claims Act which governs the release, is found in 31, U.S.C., Section 37(b)(1).

And in relevant part, that provides that, "A person may bring a civil action for violation of Section 3729 for the person and for the United States. The action shall be brought in the name of the government."

And the relevant language is, "The action may be dismissed only if the Court and the attorney general give written consent for the dismissal and the reasons for consenting."

Now, as Mr. Scheff pointed out, there is no Third Circuit law directly on point. The only case in the Third Circuit which alludes to this, as Mr. Scheff pointed out. is Rodriquez v Our Lady of Lourdes Medical Center, 552 F.3d 297 at page 301, and what the Third Circuit mentions there is that, "Although this court has not yet ruled on the matter, most courts have held that the government retains the right to veto any settlement agreement reached by a private False Claims Act plaintiff."

And it refers three circuit court decisions. It refers to United States Ex Rel Ridenour, R-I-D-E-N-O-U-R, v Keyser Hill Co., LLC, a Tenth Circuit 2005 decision which says in relevant part, "Even where the government has declined to intervene, relators are required to obtain government approval prior to entering a settlement or voluntarily dismissing the action."

The second case is United States v. Health Possibilities, PSC, 207 F.3d 355 339, a Sixth Circuit case cited in 2000, which holds that Section 3730(b)(1) provides the government with an absolute veto of any proposed qui tam settlement because the plain language of the statute does not limit this right.

And, finally, it refers to Searcy,

S-E-A-R-C-Y, v The Phillips Electronics North American Corp, 117 F.3d 154 at pages 159 and 160, a Fifth Circuit 1977 decision which holds that Section 3730(b)(1) is "unambiguous as one can expect" and that the statute plainly requires the government's consent to settlements and dismissals of Federal Claims Act actions.

THE COURT: Mr. Orlofsky, do those cases involve qui tam cases where the government has chosen to intervene?

MR. ORLOFSKY: They do not.

THE COURT: Okay.

MR. ORLOFSKY: They do not. But let me --

THE COURT: As with this case?

MR. ORLOFSKY: That's correct, Your Honor, but let me --

THE COURT: Okay.

MR. ORLOFSKY: -- let me finish my thought.

THE COURT: Okay.

MR. ORLOFSKY: The cases which Aventis relies upon, United States Ex Rel Holley (ph) v. Teledyne and United States Ex Rel Radcliffe v. Perdue Farm, LLP, a Ninth Circuit 1997 decision and a Fourth Circuit 2010 decision, involved cases where the relator had signed releases prior, and this is important, Your Honor,

prior to filing a qui tam action, not after a qui tam action was filed. And so the courts in both instances found the releases to be effective.

Now, the statute does not talk about releases signed prior to the filing of a qui tam action. Now, Aventis may not like it, but that's -- I think that Aventis and for that matter, Mr. Gohil, are stuck with the language of the statute. And as one of the courts, one of the circuit courts which I just cited says, the language is unambiguous and that the government must consent to the dismissal or the release of the qui tam action.

And I'm -- and the release here was signed, and I don't think -- I think it's undisputed -- over three years after the qui tam action has been filed. And so I think that the release just as a matter of statutory interpretation is just ineffective.

Notwithstanding the arguments which Mr. Scheff advanced about what the government knew and when it knew it, it just, as a matter of statutory interpretation, the release was ineffective.

And the release itself, which is attached to the papers which have been filed by Aventis, and nobody disputes that the release was signed and what the release says, the release says it's governed by New

Jersey -- by New Jersey law, and I submit that the release -- whether the release is effective is a question of federal law, not state law.

And so regardless of what New Jersey law may say about the scope of releases and whether the release is effective as a matter of state law don't matter, that it's a matter of federal law and there are three circuit courts upon which -- to which I've just referred Your Honor which have said that a release which is signed after a qui tam case has been filed are simply not effective unless -- unless the government consents.

Now, I'm sure that Your Honor knows after having read the -- read the briefs that there is certainly a vigorous disagreement between the parties about what happened and what legal conclusions are to be drawn from the facts in this case.

I don't think the facts are really -- are really in dispute. And I -- you know, what's interesting about this is, you know, the timing. I don't think there's any dispute about when the CEPA -- the CEPA action was filed and when the first amended complaint was filed. The CEPA action was filed on August 23rd, 2002, and the first amended complaint was filed on July 23rd, 2002.

Aventis contends that the -- the CEPA action was used by Mr. Gohil as a discovery device in support of the qui tam case. And we contend and we -- and we said this if you -- in footnote 18, which appears at page 15 of our brief, that -- that just -- that it's just disingenuous for Aventis to make the argument that -- that the discovery which was taken in the CEPA action was used to conduct discovery in support of the qui tam action.

First of all, as a matter of -- as a matter of timing, that couldn't have happened because the first amended complaint had already been filed shortly after -- hadn't -- no discovery had occurred in the CEPA action when the -- when the first amended complaint has been filed.

Now, I think -- I'd like to hand up -- if I may approach, Your Honor, I'd like to hand up Exhibit H to our brief.

(Pause in proceedings.)

MR. ORLOFSKY: May I approach, Your Honor?

THE COURT: Yes, sure.

(Pause in proceedings.)

THE COURT: Thanks.

(Pause in proceedings.)

MR. ORLOFSKY: Your Honor, I'd hate to say

that a picture is worth 1,000 words because this is a word picture which contains much more than 1,000 words, and Your Honor had a lot of -- a lot of words before you in the various briefs and exhibits which have been filed in this case by both sides.

But, what Exhibit H is an attempt to do is to compare the allegations of the amended qui tam complaint with the first amended qui tam complaint to demonstrate to Your Honor what was contained in the two complaints.

Now, Mr. Scheff, you know, very eloquently and somewhat, if I may say, cavalierly said that basically they're the same and that having been turned down by the government with respect to Anzemet, Mr. Gohil regrouped and focused on Taxotere.

And this is an effort to demonstrate to Your Honor that -- essentially, that there were very few changes substantively between -- between the two complaints, and we went through that analysis in our -- in our brief.

As Your -- as Your Honor is aware, the -- God help us, the Third Circuit has adopted an algebraic formulation to determine whether there has been a public disclosure.

It appears in the Dunleavy case and was taken

by the Third Circuit from a DC circuit case. It's if X plus Y equals Z, where Z represents the allegation of fraud and X and Y represents essential elements, in order to disclose the fraudulent transaction publicly, the combination of X and Y must be revealed.

And we have gone -- we've taken -- we've gone through the analysis in the brief with respect to the four counts of the complaint, and I won't take Your Honor through that because it's a tedious, time consuming process, but we've undertaken -- we've undertaken that analysis.

And as you can see, Your Honor, we come -- we come to a different conclusion than does Mr. -- respectfully, than does Mr. Scheff with respect to -- with respect to what the second amended complaint says.

Now, you know, what I think -- what I think is important -- what I think is important for Your Honor to understand is that we have -- obviously, we have not had the benefit of any discovery. You know, Mr. Scheff sort of says that, you know, we -- we, Gohil and his lawyers, have stonewalled him. I mean this --

I think it's fair to say that yes, this case has been litigated ferociously, not just by Mr. Gohil's lawyers, but by Mr. Scheff and his colleagues. I don't think -- you know, I don't think Mr. Scheff has been

shy about litigating this case either, and I'm not -- certainly not being critical, but I think both sides have been zealous in representing their respective clients, and that's just the way these cases proceed.

So -- but I, you know, no quarter has been asked and no quarter has been given and yes, we did -- you know, we did litigate vigorously and I think Mr. Scheff ultimately got whatever the courts ordered Mr. Gohil to provide.

So, I don't think he can say that he didn't get whatever he ultimately sought, whatever the courts ultimately directed us to provide. So he's -- whatever -- whatever jurisdictional discovery he sought he ultimately received from the courts.

Now, he's made -- he's made a couple of arguments here about some other things. I'd like to show Your Honor -- he made reference to a public disclosure contained in a Wall Street Journal article which I would like to hand up to Your Honor.

(Pause in proceedings.)

MR. ORLOFSKY: This is the so-called -- I only have one copy, Judge. This is the so-called September 15th, 1997, article, which appeared in the Wall Street Journal.

THE COURT: Thank you.

MR. ORLOFSKY: I have one extra copy. This is about a different drug, Lovenox, and there's a one sentence reference in here to Taxotere. And when Your Honor takes the time to read it, as I did the first time, you'll have trouble finding the reference to Taxotere. I had to read it once or twice. Your Honor is probably more perceptive than I am, but it took me one or two readings to find it. But, you know, I was scratching -- frankly, I was scratching my head to find out, you know, what this was all about when I read it. I'll let Your Honor obviously be the Judge of it, but it hardly, you know -- I couldn't understand what all the shouting was about. But I'll let Your -- I'll let Your Honor decide that.

So it is what it is, Judge. I -- you know, I found that I was somewhat startled when I looked at it to see what -- what all the -- what all the fuss was about. But that's what it is.

Now, you know, there's also a reference to poor Mr. Poplar, who Mr. Scheff -- Mr. Scheff is trying to throw under the bus here today --

(Pause in proceedings.)

MR. ORLOFSKY: -- who wrote some letters to the Department of Justice. There's a July 20th, 2005, letter and there is a May 18th, 2005, letter, which

I'll hand up to --

THE COURT: Sure.

MR. ORLOFSKY: -- Your Honor if I may approach. Do you have copies for --

MR. SCHIFF: I think we have all the copies.

MR. ORLOFSKY: I think Mr. Scheff has them.

THE COURT: Okay.

MR. ORLOFSKY: He's probably been highlighting them for years in anticipation of making this argument.

THE COURT: Thank you.

(Pause in proceedings.)

MR. ORLOFSKY: Judge, those letters and the language contained in those letters are not dispositive, regardless of what Mr. Poplar may have said. Mr. Scheff, you know, characterizes them as admissions. That's -- you know, that's -- that's a lawyer's argument. It's not dispositive.

Your Honor is going to have to undertake the analysis that the Third Circuit requires in Dunleavy to see if, you know, they are an admission. I respectfully submit that regardless of what language Mr. Poplar used, that it's the Third Circuit's analysis that ultimately -- ultimately will govern.

I'm a little bit taken -- oh, one other

thing. Mr. Scheff made reference to the Supreme Court's decision in the famous Rockwell case, which involved the engineer out in Colorado who was a relator who was at a nuclear power plant involving concrete blocks and he predicted that the concrete blocks would fail for a particular reason, and, ultimately, they failed for a different reason.

And the Supreme Court ultimately concluded that he had not stated a false claim because the failure -- the ultimate fail -- the case was tried and the jury found that the concrete blocks and the leakage failed for a different reason than the reason than the reason that he originally had predicted.

Well, that's not this case, Judge. It just isn't. And you could understand why the Supreme Court reached the conclusion that it reached. Rockwell is certainly distinguishable from this case.

Now, I heard an argument today, and I'm certainly not being critical of Mr. Scheff, because as he points out correctly, jurisdiction can be raised at any time. And I'm not being -- I'm not suggesting that he stole the march or that he did anything untoward, but I'm hearing for the first time the argument that there was a 12-day discrepancy about when Mr. Gohil disclosed the information to the government.

I certainly -- I would like an opportunity to review that and submit a short supplemental letter to the Court about it --

THE COURT: Sure.

MR. ORLOFSKY: -- because I'm -- I just -- I'm not -- you know, I'm not complaining because he has the right to raise a jurisdictional issue at any time, as does Your Honor, but I simply would -- I'm not in the position to respond to it because I'm hearing it -- I'm hearing it for the first time. So with respect to that, I --

THE COURT: Can you get me a letter addressing that?

MR. ORLOFSKY: Yeah, a short letter, Judge, if I may, one or -- one or two pages, and we'll get it to you in the next few days. And if -- obviously, Mr. Scheff is free to disagree with me once again about -- about the import of it, but I certainly would like to have an opportunity to look at the interrogatories he's talking -- he's talking about and that he referenced in his oral argument -- that he referenced in his oral argument today.

We said in our brief that Anzemet is not -- we're not seeking relief in the second amended complaint against Aventis for any claims based on

anzemet. We conceded that in the brief.

I'm not so -- you know, I guess today Mr. -- Mr. Scheff is saying well, you know, Mr. Gohil is essentially seeking a second bite at the apple. Having been turned down for Anzemet, he's now attempting to assert a false claim based on Taxotere while Mr. -- Mr. Gohil had exposure at Aventis both with respect to Anzemet and Taxotere. I don't know that his status is an original source for Taxotere.

Taxotere should be -- is fatal simply because he also had exposure to Anzemet. I think that our position with respect to his status as an original source with -- for Taxotere is not necessarily tainted because he also had exposure for Taxotere.

And I might add that, you know, they -- essentially, in their papers, although it's not clear from what Mr. Scheff said this morning, in their papers they seemed to at least concede that he was an original source with respect to the period of time when he was employed at Aventis before he left for Taxotere.

Now, they do contest whether he could be an original source, whether he had personal and independent knowledge with respect to his pre-employment and post-employment for Taxotere.

And I think on those issues, Judge, I don't

know if you have to actually reach that today. We're at the pleading stage here. And what the courts have said is that, you know, first of all, Mr. Gohil was trained on what we contend are Aventis' fraudulent marketing tactics and how Aventis conducted its business in the past, and he can have direct and independent knowledge, which would qualify him as an original source, for acts that occurred after he left his employment. And there's certainly case law in this circuit that talks about that. The Stinson (ph) case is one such case.

What's key is is does he have direct and independent knowledge of the key elements of the fraudulent scheme, and that doesn't necessarily require him to have been present. There could have been key elements that occurred before he got there and there could have been key elements that occurred after he left.

I just don't -- just don't think that Your Honor's in a position, nor are we, to make that determination today. And since they've essentially conceded, at least in their papers, that he was an original source certainly with respect to the time for which he was employed while -- the time that he was employed at Aventis.

I don't think you have to reach that issue and, you know, if Your Honor denies their motion, I think it will come known as no great shock to Your Honor that if the complaint proceeds, we're going to be back before Your Honor at some point in this case on summary judgment, and that issue I'm sure will be raised again. But I don't think that Your Honor necessarily has to reach that -- that issue today.

So I think I -- I've addressed all of the points that -- well, there's one other point. There was some -- there was some discussion by Mr. Scheff about the DDMAC letters, and I think -- I think we talked about that in our brief. Mr. Gohil was -- was actually deposed about that during his -- during the jurisdictional discovery that was taken in this case. Give me a moment here.

(Pause in proceedings.)

MR. ORLOFSKY: He was certainly deposed about the DDMAC letters and the sham disciplinary proceedings against his superior. And I think he talked -- although he didn't have them or he may have -- he may have come across them during the discovery in the CEPA case, he testified that he was certainly aware of them while he was employed at Aventis, and he was aware of the sham disciplinary proceedings against -- against

Buffone (ph) and the DDMAC -- DDMAC letters.

And I think that -- we did attach those as Exhibit E to our brief, and I think he -- what he did say is that -- that he -- that that information he did obtain during the course -- during the course of the discovery in the CEPA case, but he was certainly aware of that while he was employed, employed at Aventis. So he knew about that stuff, he just didn't have it and he came across it -- he came across it in the CEPA case.

I might add, Judge, that that's not necessarily a transaction or allegation within the meaning of the Federal False Claims Act. It's information, and information does not trigger the jurisdictional bar.

It's only transactions or allegations that trigger the jurisdictional bar, and we describe that I think in our papers as evidentiary materials in support of the claim.

So I think that's the only other thing that Mr. -- you know, Mr. Scheff talked about that being on the -- on the website, and I just don't think that that's critical here. So unless Your Honor has any questions, I think I've covered, or I certainly hope I've covered Mr. Scheff's presentation.

THE COURT: Thank you, Mr. Orlofsky.

MR. ORLOFSKY: Thank you, Your Honor.

THE COURT: We're going to take just a short break. I know you're dying to respond to what he said.

MR. SCHIFF: Only for three or four minutes, Judge. We can obviously take a break as the Court desires.

THE COURT: Let's take a -- let's take a short break. We've been in here about an hour and a half.

MR. SCHIFF: Sure.

THE COURT: And we'll just take a five to ten minute break.

MR. ORLOFSKY: Thank you, Your Honor.

THE COURT: All right, thank you.

(Recess, 10:21 a.m. to 10:32 a.m.)

MR. SCHEFF: -- ... 2002 because Mr. Gohil didn't comply with the statutes. He filed he qui tam case first on May 17th and then he made his disclosures to the government on May 29th.

As Mr. Orlofsky says, you know, we live and die by the plain language of the statute, and the plain language of the statute provides for that. So this case should have been dead on arrival in 2002. Mr. Gohil is not entitled to be a relator.

The second reason why it applies to the

entire case, not just the time periods before and after, although it obviously does based on the public disclosures that we provided, is the Wall Street Journal article because that discloses the scheme relating to Taxotere (inaudible) to grants.

And, you know, it doesn't matter whether Mr. Gohil knew of that article, didn't know of that article. It's a public disclosure. And, honestly, it doesn't matter whether it's one sentence, two sentences, three sentences, but it is more than one sentence.

So, there is no subject matter jurisdiction in this case. And the Court -- it's pretty clear that the statute provides that under these circumstances. We've had discovery. This case should not be going to summary judgment on that basis, discovery shouldn't go forward on that basis.

With respect to the argument that -- this claim by claim analysis argument that Mr. Orlofsky makes, again, I would refer the Court to the Rockwell case, and our description of the Rockwell case on this particular point is located in footnote 32 of our principal brief.

You really have to look at the facts that are alleged, and it's a different scheme that is alleged in

the first amended complaint versus the second amended complaint, and you can't have a trivial claim of fraud alleged and try to preserve claims that way. It doesn't work that way, and that's what Rockwell says. So the first amended complaint simple comparison to the second amended complaint demonstrates they are different theories, different claims.

I'll turn very, very briefly to the release. You know, we agree with Mr. Orlofsky, and it's in our brief, the scope of the release is governed by New Jersey law, broad, unequivocal, no exceptions.

The enforceability is governed by federal law, that's Rumery. It's a public policy analysis. It's not the statutory analysis that Mr. Orlofsky refers you to because we're not trying to boot the government from making the claim.

All we're trying to say to the Court and all we're saying is is that Mr. Gohil can't be a relator. And we agree with the government that if the Court finds that the release is effective and broad and that the public policy reasons that I've argued in my principal argument apply, and we think they do, the government had adequate opportunity to examine the facts of this case, then the Court ought to dismiss the case without prejudice, and Mr. Gohil can't proceed as

the relator. If the government wants to, then the government then can choose to. Thank you, Your Honor.

THE COURT: Thank you.

MR. SCHIFF: I'm going to turn this over to Mr. McCully.

(Pause in proceedings.)

THE COURT: Good morning, Mr. McCully.

MR. McCULLY: Good morning, Your Honor, and I will try to be brief in my remarks. I want to switch gears just a little bit here and switch from discussions of jurisdiction and releases to a discussion of adequacy of pleadings.

Although I will submit as I sat listening to the argument that there are overlaps. And one of the things that we will talk about here this morning is Rule 9(b)'s requirement that averments of fraud be pled with particularity and that there are some courts who continue to hold to a stance that that requires in a False Claims Act case for actual false claims to be included with the complaint.

Again, as I sat here listening to the argument about did the first amended complaint, the second amended complaint, did those -- are they the same complaints? Are they two completely different ones? I couldn't help but be struck by the notion that

if we required FCA relators to provide particular allegations with respect to the entire False Claim Act starting from the private scheme all the way through the claim itself, we might not have some of those difficulties of trying to understand exactly what it is that they are claiming in the case.

I think we also find that we have been subjected somewhat, and I'll talk about that again in my remarks here today, to the notion that we're sometimes toting a little bit of a moving target in terms of what the allegations are. And, again, that's because we have not been provided with details of the entire alleged violation all the way up to the time of the claim itself.

So let me back up just a little bit then we'll get back to that point. The complaint falls in several respects to comply with Federal Rule of Civil Procedure 9(b) and with 12(b)(6), providing some additional bases on which to dismiss the second amended complaint.

Federal Rule 9(b) requires that all averments of fraud or mistake that the circumstances constituting the fraud or mistake shall be stated with particularity. And there's no dispute that actions brought under the False Claims Act must comply with the

strictures of Rule 9(b).

Third Circuit law clearly states that 9(b) requires at a minimum that a plaintiff supports its allegations of fraud with all the essential factual background, that is the who, the what, the where, the when, and the how of the events at issue. That comes from the Third Circuit case Rockefeller Center Properties litigation.

The purposes of 9(b) have been explained as threefold and, again, this is -- this is from the In Re: Burlington Coat Factory case, the Third Circuit case back to 1997.

And the Third Circuit back in 1997 said that we see that there are three purposes to Rule 9(b). One is to give defendants notice of the claims against them. Again, that goes a bit to the statement I made a little bit earlier in terms of trying not to tilt at a moving target here from the beginning, that we have notice of exactly what claims are being brought against us so that we can provide and mount the appropriate defense.

Two is to provide defendants an increased major protection for their reputations. In other words, make the plaintiff provide enough detail so that it's not seen as just an exercise in throwing down some

words on paper at the damage to the defendant's reputation.

I think the third one that the Third Circuit stated in Burlington Coat Factory is also a very important one to remember, and that's to reduce the number of frivolous suits brought solely to extract settlements.

These three purposes, again, to Rule 9(b) require the pleading of the who, what, the where, the whens, and the hows. And in the context of an FCA, a false claims case, the allegations of fraud to be stated with particularity must include the false claims themselves. That is statements that have been made by numerous courts within the Third Circuit. That is it's not enough to merely describe a private scheme in detail and then conclude that false claims must, therefore, have been submitted. There must be some -- some detail given about false claims themselves.

So we have two things to analyze in the Rule 9(b) context. First, the alleged private scheme by Aventis, and second, the means -- or excuse me -- the nexus between that scheme and the filing of a false claim such that we have an actual violation of the False Claims Act.

Without that nexus, that causal connection,

and the false claim, the private scheme alleged by Gohil to have existed at Aventis does not in itself violate the False Claims Act.

So first, the alleged private scheme, it's important to note and, again, this goes somewhat hand-in-hand with some of the remarks made by Mr. Scheff regarding Mr. Gohil's times of employment and his direct and personal knowledge of circumstances.

But if you look at the second amended complaint, the earliest dates set forth in the complaint are 2001, which makes sense, given that the relator would not have had personal knowledge of events at Aventis prior to his joining Aventis in December of 1999.

I didn't find allegations prior to 2001. There may have been some in there in 2000. But they clearly couldn't -- there clearly were no dates given of circumstances under this fraudulent marketing scheme prior to 1999.

Mr. Gohil wants to claim damages for a period of time in 1996 to 2004, but he doesn't provide any sense of particularity for any actions that occurred prior to his joining in 1999. The who, the what, the where, the when, and the how details just simply aren't there from 1996 to 2000, and that in and of itself

violates Rule 9(b) and certainly is in itself grounds to at least dismiss that part of the complaint that seeks damages prior to the time in which we are given details about the alleged fraud.

With respect to the time periods from 2000, 2001 forward and Gohil begins pleading some of the who, what, when, where info, his second amended complaint is sufficient primarily in the second part of the Rule 9(b) evaluation, are there actual false claims and is there a causal connection between the alleged activities of Aventis and these false claims?

Now, our briefing in this matter, and again, we filed that briefing several years ago, but our briefing in this matter argued for the need of the presentment with a complaint of an actual false claim submitted, the false claim being the signed qui non of an FCA action.

Our brief and our reply brief detailed the many courts that have adopted this holding as a part of the Rule 9(b) requirement in False Claims Act cases including the Eighth and Eleventh Circuits and the Third Circuit in the context of a summary judgment motion, that there actually be false claims submitted in order to withstand the motion to dismiss or in the case of the Third Circuit case to withstand the motion

for summary judgment.

The Third Circuit did rule in the Quinn case, and it was reiterated just a couple years ago in the Wilkins case that at summary judgment there will come a time in any FCA action in the Third Circuit wherein actual claims are going to have to be presented. So, it is not that you can rely upon the pleading of a scheme and then continue to presume that false claims were actually filed. False claims are going to have to be presented at some point in time.

We made the argument in our briefs that now is the time to do that based upon the rulings of numerous courts and based upon the rulings of courts in the Eighth and Eleventh Circuits, based upon rulings of courts in this Circuit that were in existence at the time.

And based upon the fact that this is a case that at the time we filed our motion to dismiss in 2010 and then replied in 2011 had been around for nine years if you go all of the way back to 2002. The second amended complaint had been around for four years at that point in time if you go back to its filing in 2007.

Plenty of time, under the circumstances of this case, if Mr. Gohil was a true individual with

direct and personal knowledge and a true original source to have gathered together at least some examples of these false claims.

Given the fact that this is a case where the defendant, Aventis, is not in possession of false claims, the argument often heard is let us do discovery and we will find those claims once we are able to get them from the defendant, that's not going to be the case in this particular matter. This is a third party filing case, Aventis does not have those claims in its possession.

So, we made that argument back in 2010, 2011, and, you know, we continue to stand by that argument not so much because the cases require claims to be presented to the Court, but because the cases do require a pleading of particularity and the cases do require that if you don't have a claim submitted that you have to have satisfied this particularity requirement by some alternative means of injecting precision and substantiation into your allegations of fraud. And, again, there can be no fraud without the ultimate filing of false claim.

If Mr. Gohil's complaint injected some other alternative means of precision and substantiation, we would not necessarily be here asking for an actual

false claim, but it does not.

His complaint sets forth paragraphs about the alleged private scheme at Aventis and then asks this Court to simply jump to the conclusion that the messages supposedly given by Aventis were heard, the messages supposedly given by Aventis were heard and complied with, that doctors acted upon those messages to the absence of any other sort of medical judgment decision, and that those doctors then sought reimbursements for treatment that were not medically necessary.

That's a lot of jumps to make from one set of events happening to the necessary set of events happening, which is that a false claim for a medically unnecessary treatment was filed by a doctor and that that doctor made all of those decisions based upon any sort of alleged misconduct by Aventis, and we simply don't think that the complaint has that in it.

If Mr. Gohil had some actual false claims to show us that met those things, that would be one way to meet the requirement of Rule 9(b). He has not given us that.

We have to look at the complaint itself and the complaint itself doesn't have the necessary detail of particularity in it to withstand a Rule 9(b)

scrutiny and should be dismissed on those grounds.

And again, any argument that -- Judge, this is a motion to dismiss stage, and we can do discovery, it just simply does not make sense in this particular aspect where, again, the information to be found is not going to be in the hands of the defendant, and the information that is missing is something that if Mr. Gohil did, indeed, have this direct and personal relationship and knowledge that these things were happening could have been something that he independently obtained, the government has had this case for a number of years and certainly has all of the tools at its disposal to conduct investigations and has not come forward with any sort of ways to fill in those gaps. So, that's where we are with 9(b).

Let me turn real quickly to a couple of 12(b)(6) arguments, although again there is still some 9(b) that overlaps in there. First deals with Count 1, the conspiracy claim.

We argued in our briefs that Mr. Gohil's Count 1 should be dismissed because it fails to state a claim as a matter of law. His Count 1 is that Aventis conspired with its sales force, its outside consultants and various healthcare providers to violate the False Claims Act in violation of Section 3729(a)(3) of the

False Claims Act. The problem with Mr. Gohil's Count 1 is that the notion of a conspiracy doesn't show up anywhere else in the complaint.

In fact, the entire gravamen of the second amended complaint is that Aventis engaged in this fraudulent marketing scheme to unduly influence doctors to make bad medical decisions and to then file claims for reimbursement for those prescriptions that resulted from those decisions.

The entire gravamen is that this was an Aventis deal. There are no specific doctors named in the complaint who bought into this thing, and there certainly is no statement at all in the complaint of any sort of an agreement or meeting of the minds to violate the False Claims Act.

There are no statements of a meeting occurring between Aventis and healthcare providers, notes and because of that, no statements about when such a meeting happened, where such a meeting happened, how such a meeting happened and what was decided.

All we have is that Aventis engaged in certain events, off-label marketing and kickbacks, doctors must have engaged in some certain events prescribing and filing for reimbursement. There is no attempt anywhere in the complaint to connect those two

together until we get to three paragraphs in Count 1, which is conspiracy.

THE COURT: Who are the alleged co-conspirators for Count 1?

MR. McCULLY: Who are?

THE COURT: Yes

MR. McCULLY: Sales force and outside consultants which we argue is that's simply impossible to conspire with your own agents. They enter corporate conspiracy doctrine and, again, Mr. Gohil concedes that that's not what he intended by his conspiracy count. His conspiracy count, he states that his intent really was to get to any agreement between Aventis and healthcare providers.

There are healthcare providers named in Count 1 by letter, by an alpha letter, but again there is nothing within the body of the complaint itself which suggests that any meetings ever occurred or any agreements ever existed between Aventis and these healthcare providers until we get to that conspiracy count.

THE COURT: All right. Thank you.

MR. McCULLY: And then with respect to Counts 3 and 4 of Mr. Gohil's complaint, those deal with violations of 3729(a)(1), false claim, 3729(a)(2), a

false statement to cause a false claim.

We argued in our brief again that to the extent that Mr. Gohil is alleging that these violations occurred because of an off-label marketing on the part of Aventis, that those claims could not go forward because they fail to state a claim.

Mr. Gohil is seeking damages for any claims made for reimbursement for off-label uses of Taxotere. That is not the standard. An off-label use of a product is, you know, generically understood to mean something that is different than the indications listed in the label. I think that's how we all understand off-label.

But, the Medicare statute and regulations at issue here don't restrict the reimbursement for a product to on-label, indicated uses. That is one of the diagnoses for which Medicare will reimburse, but it will also reimburse for anything that is considered to be a medically accepted indication.

And we can look to not only the product label, but to certain published drug compendia to determine whether or not the product has a medically accepted indication.

If we look at Mr. Gohil's complaint we are dealing with Taxotere. Taxotere up until 2002 had two

labeled indications, second line treatment for non-small cell lung cancer, and second line treatment for breast cancer.

The compendia that we can use in addition to the label to determine whether or not Medicare would have paid these claims also included each of those two treatments of cancer in a first line regimen, as well as small cell lung cancer, ovarian cancer, prostate cancer, bladder cancer, gastric cancer and esophageal cancer, and these compendia are listed in Exhibits 14 to 16 of our motion to dismiss.

Any claim for reimbursement under which a provider listed one of those diagnoses as a part of the claim would have been treated by Medicare as something medically accepted in terms of an indication and the claim would have been paid.

The only two off-label promotions that Mr. Gohil talks about in his complaint are first line non-small cell lung cancer and ovarian cancer. Again, both of those indications were listed in medical compendia as early as 1998. That's Exhibit 14 to the motion to dismiss.

Mr. Gohil in his response indicated that I am not limiting my off-label comments to just those two medical situations. My complaint is broader than that.

To the extent that that's his response we once again run afoul of Rule 9(b). We see in the complaint specific allegations about non-small cell lung cancer, first line and ovarian cancer.

We argue that there is a defense to that. We are then told no, I meant more than that. Again, it comes back, it all comes full circle again. If we had particularity to begin with, if we had some claims to begin with then we can start to see what it is that we actually have to defend ourselves against here.

Viewed holistically this complaint simply does not have the degree of precision in it that allows Aventis to muster a defense and be assured that as it puts a defense together that that target won't move on it, and I think that that's a real basis for why Rule 9(b) exists and a real basis -- and I think we have real world examples here of why it has not been working.

Again, we anticipate that you will hear and I am sure this Court is well aware that there have been a number of decisions since we filed our briefing of courts in this very courthouse that have determined that it is not necessary to have a specific claim in order to withstand a Rule 9(b) motion at the motion to dismiss stage, and we are not going to argue with that.

We are suggesting that none of those courts have stated that that's not a bad idea or that that's a bad idea, I am sorry, to include those kinds of claims.

Each one of those courts has suggested there has to be something additional to inject some precision substantiation into the complaint to show that we've got a scheme and we've got a connection there between the scheme and the false claim itself.

We are simply suggesting that in this particular case, given the amount of time that has passed and given the apparent lack of this relator to show personal experiences of doctors that have prescribed based upon an off-label promotion or a kickback scheme that false claim may be his only way to get us that level of precision, substantiation.

Since that is missing we don't have Rule 9(b) complied with. Even if we do we've got issues with Counts 1, 3 and 4, and Rule 16, excuse me, Rule 12(b)(6) grounds as well as we laid forth in our brief, and with that I will close, Your Honor.

THE COURT: Thank you, Mr. McCully.

MR. ORLOFSKY: Your Honor, I say here and listened attentively to Mr. McCully's presentation and it took me back. Your Honor, if you'll permit me a brief historical exposition.

I began my career clerking, and I won't tell you when, for Mitchell H. Cohen, who was the chief judge in the District of New Jersey for whom the courthouse across the river is now named.

And I began as a law clerk and the first case that came across my desk was a case called Connolly v. Gibson, which has now fallen into disuse. It's a Rule 56 case, and it was rather liberal in terms of what the standard was for granting motions for summary judgment.

Then as I went into private practice with Blank Rome, Ed Rome, one of the greatest lawyers of the republic, and I went to the United States Supreme Court to argue a case called Matsucha (ph), which I'm sure Your Honor has heard, which we lost much to our surprise, you know, in the Supreme Court five to four on what was found to be and what everyone now talks about as a plausibility argument. And now we have, much to my surprise, Twombly and Iqbal.

Today, I find myself hearing about Rule 8(b) and thinking have the Federal Rules of Civil Procedure closed the courthouse doors entirely? And I respectfully submit, Your Honor, that that's not the case, and let me tell you why -- why I believe that that's not the case.

First of all, we have cited in -- as Mr.

McCully pointed out, there are cases within this district which adopt a much more generous standard with respect to motions to dismiss based on 8(b), and we've -- we've cited those cases.

We principally rely upon Underwood and Schuman decisions by Judge Ditter and Judge Diamond, and we have also pointed out to Your Honor the Third Circuit's decisions -- decision in Civil Industry Machinery Corp. v. Southmost Machinery Corporation, which is a 1984 decision of the Third Circuit.

More importantly, Judge, and Mr. McCully sort of referred to it but didn't say it, is the Third Circuit's decision in Wilkins, United States Ex Rel Charles Wilkins versus United Health Group, 659 F.3d 295, decided in 2011, which was provided to Your Honor, I guess it was provided to Judge Tucker and to Your Honor who succeeded her in this case by way of supplemental authority, and we think Wilkins has effectively changed the legal landscape with respect to federal FCA cases.

What did Wilkins say? Well, it said a couple of things, and for one thing, it made clear and it said, "But to our knowledge we have never have held that a plaintiff must identify a specific claim for payment at the pleading stage of a case to state a

claim for relief," citing Fowler versus UPMC Shadyside, 579 F.3d 203 213, Third Circuit, 2009.

So, if there was any doubt about that, the Third Circuit clarified that a plaintiff at the pleading stage in a -- in a FCA case does not have to identify a specific claim for payment in an FCA case.

It went on to hold in Wilkins to adopt the implied certification theory, which had never -- which had been adopted by several courts of appeals, but had never been adopted by the Third Circuit. And, basically, where -- what that -- what that says is that if there is an allegation that a defendant violates the anti-kickback statute while submitting a claim for payment to the -- to the government, that is a violation of the Federal Claims Act, and we have alleged that, Judge.

And that -- if you -- if you take the time to read the second amended complaint, as I'm sure you will, the second amended complaint is replete with violations of the anti-kickback statute. There's no -- there's no surprise. I mean that is a perceived violation of the Federal Claims Act.

We've stated a claim and we're at the pleading stage, Judge. We're not at the summary judgment stage. And if we were at the summary judgment

stage, then perhaps Mr. McCully's argument both with respect to the -- the 8(b) argument and the 12(b)6 argument might carry more force. But we're not there yet.

And the same -- the same argument is true with respect to the conspiracy claims, I mean we have alleged. You know, it's -- you know, I -- you know, the complaint -- a complaint, Judge, does not have to be perfect. It does not have to be a model of perfection. It simply has to put the defendant on notice of the misconduct with which he, she, or it is charged, and it does that.

If you take a look at that, there are allegations of what the conspiracy is. Now, it may not be as detailed as Mr. McCully would like it. But, for example, if you look at -- just to take an example, and I'm not going to go through the whole complaint. Your Honor has it and at your leisure, if you have any, Judge, you can look at it. But, just look at paragraph 190. I'll just read it to you as an example.

"Between at least 1996 to January 2004, the defendant, Aventis, various healthcare providers" -- now, if we knew who they were, Judge, we would identify them, but this is a pleading stage, "Aventis' outside consultants, and members of Aventis' sales forces,"

okay, the intercorporate conspiracy doctrinating they can't conspire with themselves, but they can certainly conspire with various healthcare providers and outside consultants, "knowingly combined and conspired with each other to violate the False Claims Act by acting in concert to defraud the government by getting fraudulent claims allowed and paid relating to Taxotere and violation," et cetera, et cetera.

Then it says, paragraph 191, "The healthcare providers that submitted false claims for payment to the government include, but are not limited to, hospitals, A-G, group practices, A-B, and the John Doe defendants." That's all that needs to be alleged in a complaint, Judge.

It doesn't have to be perfect and it doesn't have to be specific, and John Doe pleadings are allowed, not only in -- certainly in conspiracy cases. You know, conspirators don't, you know, stand up and raise their hand and say Your Honor, I'm a conspirator, I'm a co-conspirator.

And, you know, Mr. McCully says well, you know, they can't say that they -- Aventis doesn't know. They can't take discovery from Aventis and find out who the conspirators are.

Well, you know, there's Rule 45. We can take

conspir -- you know, discovery of third parties, and we're entitled to do that. So it's not -- it's not an answer to say that Aventis -- even if we were to take discovery of Aventis, Aventis couldn't answer those questions. Somebody could.

So 8(B), even though it requires pleading fraud with particularity, doesn't close the courthouse door. And even in Wilkins the Third Circuit said that at the pleading stage the standard is different. And Rule 56, okay, summary judgment, yeah, I understand. And then, you know, something -- you know, the standard is different, but we're not there yet.

We certainly overcome Twombly and Iqbal. This is not a conclusory pleading. This is not an implausible pleading. We are passed Matsucha, we are passed Twombly and Iqbal.

Maybe it's not a perfect pleading, but it is certainly a pleading which gets passed a motion. And for those reasons, Judge, I respectfully request that you deny the motion to dismiss based on 8(b) and 12(b)(6).

THE COURT: Thank you, Mr. Orlofsky.

MR. ORLOFSKY: Thank you, Your Honor.

(Pause in proceedings.)

MR. McCULLY: May I come up?

THE COURT: Sure. Sure.

(Pause in proceedings.)

MR. McCULLY: And I will be very brief. Two points. One, on the conspiracy argument, again, there's no doubt that paragraphs 190 and 191 allege a conspiracy.

Again, as my statements to you earlier, Judge, were that that is the -- those paragraphs are part of Count 1 itself, and in the preceding 189 paragraphs of complaint there's not one mention of an agreement between Aventis and any healthcare provider to commit fraud.

This is a fraud case, all False Claims Act cases are. Conspiracy to commit fraud is governed by Rule 9(B) as well, so it requires more than a Rule 8. It requires particularity, and the courts in this circuit have interpreted that to include identifying who, what, where.

The statement that if we had known who these conspirators are, we would have named them speaks volumes. At this point in time, in a false claims case brought by a relator with direct and personal knowledge, if there is a conspiracy count, it needs to be known at this point in time who those conspirators are.

This is not a situation or should not be a situation where we can throw that count out there and then do discovery and see if we can come up with facts to support it. And so that's where we are in the conspiracy count. We believe it does not comply with Rule 12 and with the heightened requirements of Rule 9 and this pleading should be dismissed.

With respect to the Wilkins case, Your Honor, I did not leave Wilkins out of my comments to you out of any sort of intent, and I just want to make certain that that's clear.

Wilkins case was decided by the Third Circuit in 2011. It does contain the statement that, to our knowledge, we have never required the presentment of a claim to withstand a motion to dismiss on Rule 12(b)(6) grounds. That's what was in front of the Wilkins court.

My Rule 9(b) argument is that the Wilkins decision did not change the landscape of Third Circuit law at all. That is still an undecided issue, quite frankly, in front of the Third Circuit, is does 9(b) require the bringing forth the specific false claims to withstand a motion to dismiss?

What the Wilkins court said was following that statement that we're not aware of a requirement

that you bring forward a false claim to withstand 12(b)(6).

It went on in the very next paragraph to talk about Rule 9(b), first noting that that issue was not directly in front of them, so they were not going to make a decision on it, but also noting that there is a heightened standard to meet Rule 9(b) and certainly leaving open the possibility that they might require a claim to be presented to withstand Rule 9(b). But they didn't have to reach it that day because that was not in front of them.

What happened to the Wilkins case after the Third Circuit decision, it remanded back to the district court for the district court to determine whether or not the plaintiff relator had met 9(b) requirements with respect a second count claim for relief, and the district court granted the motion to dismiss because there was not a single claim, false claim presented as a part of the complaint. That's how the Wilkins case ended up, or at least as far as the decisions thus far.

I have to admit I don't know if that case is up on further appeal to the Third Circuit or not. I do know that the most current standing is it's in a dismissed state as a result of the trial judge's

finding that 9(b) requires a claim.

We are not suggesting the courthouse doors are closed, but we are suggesting that there are rules to be followed and those rules apply in these False Claims Act cases.

There have been other courts in this division that have found that a single claim is not required. Again, we're not suggesting that a single claim is the only way that Mr. Gohil could meet his requirements here.

We're saying that he hasn't met that requirement, nor has he met any other requirement of showing the necessary particularity to come from a fraudulent scheme alleged to have occurred at Aventis and doctors filing false claims for reimbursement based upon that scheme. Thank you, Your Honor.

THE COURT: Thank you, Mr. McCully. It's a very complex case and I know you've been waiting for quite some time for an answer on this motion, so we'll get this on an expedited track and get a decision out to you as soon as we possible can.

Thank you very much for your really comprehensive and enlightening arguments this morning. It's a great help in understanding the arguments you've raised in your papers, I appreciate it.

MR. ORLOFSKY: Judge, may we just have a few days to submit a short letter on that one jurisdiction --

THE COURT: Well, I won't decide this in a few days, so yes, you may, Mr. Orlofsky. How long do you need? Next week?

MR. ORLOFSKY: Yes, that will be fine, Judge.

THE COURT: So next Friday?

MR. ORLOFSKY: Yes.

THE COURT: That works?

MR. ORLOFSKY: That works.

THE COURT: Okay.

MR. SCHEFF: And, Your Honor, if we have a reply, it will be very short and very prompt.

THE COURT: Okay. Thank you very much.

ALL: Thank you, Your Honor.

(Proceedings adjourned, 11:13 a.m.)

* * *

CERTIFICATION

I, Michael Keating, do hereby certify that the foregoing is a true and correct transcript from the electronic sound recordings of the proceedings in the above-captioned matter.

2-27-14
Date

Michael T. Keating
Michael Keating